



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 2 1999 7 8 0 '99 DEC -6 P 1:47

Sanford J. Lewis, Attorney
P.O. Box 79225
Waverly, Maine 02170

RE: 99P-2077/CP

Dear Mr. Lewis:

This is an interim response to the citizen petition submitted to the Food and Drug Administration (FDA) on behalf of Health Care Without Harm (HCWH). In the petition you requested that FDA (1) initiate a rulemaking or issue a guidance requiring that all polyvinyl chloride (PVC) medical devices that leach phthalate plasticizers include a prominent, clearly worded warning label as to the potential for di-ethylhexyl phthalate (DEHP) or other phthalate plasticizers to leach out the PVC and to enter the body, potentially causing detrimental health effects, and (2) establish a program to expedite the development and usage of substitutes for PVC medical devices that leach phthalate plasticizers.

As you are aware, we met with various stakeholders in this issue, including your clients on March 11, 1999, and anticipate other meetings. Additionally, FDA is currently conducting a risk assessment of the primary phthalate plasticizer (DEHP) used in medical devices and expects its completion by January 2000. Upon its completion, we will make a decision regarding the actions requested in the petition.

If you have questions, please contact Melvin E. Stratmeyer at 301-443-7130.

Sincerely yours,

Linda S. Kahan,
Deputy Director for Relations and Policy
Center for Devices and Radiological Health

99P-2077

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